

<b>Notification of Test Changes in Medical Test Site</b>
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License # MTS-\_\_\_\_\_CLIA #\_\_\_\_\_Fax #\_\_\_\_\_  
 MTS Name \_\_\_\_\_Effective date of change\_\_\_\_\_

List tests added to or deleted from your Medical Test Site	Estimated annual test volume

► For added tests where proficiency testing is required, provide evidence of enrollment (See attached list)

► If the added tests change your site to a higher complexity level (i.e., waived or PPMP to moderate or moderate to high), you must provide information about the **qualifications** of **key personnel** and the **director's signature**:  
**Moderate** complexity testing on **this page**; **High** complexity testing on the **next page**

<b>QUALIFICATIONS OF PERSONNEL FOR MODERATE COMPLEXITY TESTING</b>
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**DIRECTOR** (Check only one)

1. \_\_\_\_\_ Pathologist with State license
2. \_\_\_\_\_ MD, DO, DPM with State license and 1 year directing or supervising non-waived testing  
     Which laboratory \_\_\_\_\_ Dates \_\_\_\_\_
3. \_\_\_\_\_ MD, DO, DPM with State license and 20 CMEs in laboratory practice  
     Which program \_\_\_\_\_ Dates \_\_\_\_\_
4. \_\_\_\_\_ MD, DO, DPM with State license and lab training during residency equivalent to 20 CMEs  
     Which program \_\_\_\_\_ Dates \_\_\_\_\_
5. \_\_\_\_\_ PhD in science and board certification (ABB, ABMM, ABCC, ABMLI)
6. \_\_\_\_\_ PhD in science and 1 year directing or supervising non-waived testing  
     Which laboratory \_\_\_\_\_ Dates \_\_\_\_\_
7. \_\_\_\_\_ Master in science, + 1 year lab training and/or experience and 1 year lab supervisory experience
8. \_\_\_\_\_ Bachelor in science, + 2 years lab training and/or experience and 2 years lab supervisory experience
9. \_\_\_\_\_ On 2/28/92, serving as lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
10. \_\_\_\_\_ On 2/28/92, was qualified under State law to direct a lab

**For directors not qualified according to 1 through 5 above, complete the following about the qualifications of your Clinical Consultant**

**CLINICAL CONSULTANT** (Check only one)

1. \_\_\_\_\_ Pathologist with State license
2. \_\_\_\_\_ MD, DO, DPM with State license
3. \_\_\_\_\_ PhD in science and board certification (ABB, ABMM, ABCC, ABMLI)

**SIGNATURE OF DIRECTOR**

**I certify that the information included on this form is accurate:**

\_\_\_\_\_  
**Signature of the Medical Test Site Director**

\_\_\_\_\_  
**Date**

**MD, DO, DPM**  
**Director Qualification Requirements**  
**Moderate Complexity Testing**

Individuals with an MD, DO, DPM must have a State license and must meet one of the following requirements to qualify as a laboratory director of a medical test site performing moderate complexity testing:

- **1 year directing or supervising non-waived testing**

OR

- **20 Continuing Medical Education credits (CMEs) in laboratory practice**

OR

- **Laboratory training during residency equivalent to 20 CMEs in laboratory practice**

On page 8 of the Medical Test Site License Application form, select the route by which you qualify as a moderate complexity testing laboratory director, and provide specific information about the location and dates of your laboratory experience and/or training.

**If you need to obtain the 20 hour CME credits for laboratory directors of moderate complexity testing, the following courses are available:**

**1. University of Wisconsin and COLA**

Physician's Office Laboratory (POL) Symposium: Three day meeting with national speakers and exhibits containing POL equipment.

[www.COLA.org](http://www.COLA.org) or (800) 981-9883

**2. University of Wisconsin and COLA**

Lab University: On-line laboratory director course.

[www.labuniversity.org](http://www.labuniversity.org)

These courses are designed to meet the CLIA requirement at 493.1405(b)(2)(ii)(B). They are accredited by the ACCME and are designated as AMA PRA category 1 credits.

**QUALIFICATIONS OF PERSONNEL FOR HIGH COMPLEXITY TESTING**

**DIRECTOR** (Check only one)

1. \_\_\_\_\_ Pathologist with State license
2. \_\_\_\_\_ MD, DO, DPM with State license and 1 year lab training in medical residency  
Which program \_\_\_\_\_ Dates \_\_\_\_\_
3. \_\_\_\_\_ MD, DO, DPM with State license and 2 years directing or supervising high complexity testing  
Which laboratory \_\_\_\_\_ Dates \_\_\_\_\_
4. \_\_\_\_\_ Ph.D. in science and board certification (ABB, ABMM, ABCC, ABMLI)
5. \_\_\_\_\_ Ph.D. in science and before 2/24/03, served or serving as director of a high complexity laboratory and 2 years laboratory training and/or experience and 2 years directing or supervising high complexity testing  
Which laboratory \_\_\_\_\_ Dates \_\_\_\_\_
6. \_\_\_\_\_ On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
7. \_\_\_\_\_ On 2/28/92, was qualified under State law to direct lab
8. \_\_\_\_\_ For subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology; or American Osteopathic Board of Pathology or equivalent

**For directors not qualified according to 1, 2, 3, 4 or 8 above, complete the following about the qualifications of your Clinical Consultant**

**CLINICAL CONSULTANT** (Check only one)

1. \_\_\_\_\_ Pathologist with State license
2. \_\_\_\_\_ MD, DO, DPM with State license
3. \_\_\_\_\_ PhD in science and board certification (ABB, ABMM, ABCC, ABMLI)
4. \_\_\_\_\_ DDS certified in oral pathology (ABOP, ABP, AOBP)

**SIGNATURE OF DIRECTOR**

**I certify that the information included on this form is accurate:**

\_\_\_\_\_  
**Signature of the Medical Test Site Director**

\_\_\_\_\_  
**Date**

# Approved Proficiency Testing Providers

Accutest	(800) 356-6788	California Thoracic Society	(714) 730-1944
Amer. Acad. of Family Physicians	(800) 274-7911	College of American Pathologists	(800) 323-4040
Amer. Assoc. of Bioanalysts	(800) 234-5315	EXCEL (CAP)	(800) 323-4040
American Proficiency Institute	(800) 333-0958	WSLH	(800) 462-5261
ASIM Medical Lab Evaluation	(800) 338-2746		

## REGULATED ANALYTES: These Tests MUST Be Covered By PT

### **CHEMISTRY**

ALT/SGPT  
Albumin  
Alkaline phosphatase  
Amylase  
AST/SGOT  
Bilirubin, total (or neonat.)  
Blood gas pO<sub>2</sub>, pCO<sub>2</sub>, pH  
Calcium, total  
Chloride  
Cholesterol, total  
HDL cholesterol  
Creatine kinase  
Creatine kinase isoenzymes  
Creatinine  
Glucose  
Iron, total  
LDH  
LDH isoenzymes  
Magnesium  
Potassium  
Sodium  
Total protein  
Triglycerides  
Urea nitrogen  
Uric acid

### **ENDOCRINOLOGY**

Cortisol  
Free thyroxine  
Serum pregnancy (HCG)  
(qualitative or quantitative)  
T3 uptake  
Triiodothyronine  
TSH  
Thyroxine

### **TOXICOLOGY**

Alcohol, blood  
Blood lead  
Carbamazepine  
Digoxin  
Ethosuximide  
Gentamicin  
Lithium  
Phenobarbital  
Phenytoin  
Primidone  
Procainamide (& metabolite)  
Quinidine  
Tobramycin  
Theophylline  
Valproic acid

### **HEMATOLOGY**

Cell identification  
Auto or manual WBC diff.  
Erythrocyte count (RBC)  
Hematocrit (automated)  
Hemoglobin  
Leukocyte count (WBC)  
Platelet count  
Fibrinogen  
Partial thromboplastin time  
Prothrombin time

### **IMMUNOHEMATOLOGY**

ABO group  
D (Rh typing)  
Antibody detection  
Compatibility testing  
Antibody identification  
**SYPHILIS SEROLOGY**  
RPR, VDRL, MHA-TP, etc.

### **IMMUNOLOGY**

Alpha-1 antitrypsin  
AFP (tumor marker)  
Antinuclear antibody  
ASO  
HIV  
Complement C3, C4

### **IMMUNOLOGY (cont.)**

HBsAg, Anti-HBc, HBeAg  
IgA, IgE, IgG, IgM  
Infectious mononucleosis  
Rheumatoid factor  
Rubella

### **BACTERIOLOGY**

Chlamydia  
Direct Strep test  
GC  
Throat culture  
Urine culture ID  
Gram stain  
Other culture/combinations  
Antimicrobial tests

### **MYCOLOGY**

Yeast ID/culture  
Fungus culture - systemic

### **PARASITOLOGY**

Direct only  
Concentration/Stain

### **VIROLOGY**

HSV EIA  
Culture or FA  
Other EIA for virus

### **MYCOBACTERIOLOGY**

AFB Smear and/or culture